

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO COMMITTEE PRINT  
(RELATING TO H.R. 1132)  
OFFERED BY MR. WHITFIELD OF KENTUCKY**

Strike all after the enacting clause and insert the following:

**1 SECTION 1. SHORT TITLE.**

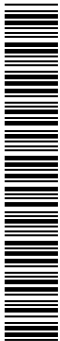
2 This Act may be cited as the “National All Schedules  
3 Prescription Electronic Reporting Act of 2005”.

**4 SEC. 2. PURPOSE.**

5 It is the purpose of this Act to—

6 (1) foster the establishment of State-adminis-  
7 tered controlled substance monitoring systems in  
8 order to ensure that health care providers have ac-  
9 cess to the accurate, timely prescription history in-  
10 formation that they may use as a tool for the early  
11 identification of patients at risk for addiction in  
12 order to initiate appropriate medical interventions  
13 and avert the tragic personal, family, and commu-  
14 nity consequences of untreated addiction; and

15 (2) establish, based on the experiences of exist-  
16 ing State controlled substance monitoring programs,  
17 a set of best practices to guide the establishment of



1 new State programs and the improvement of existing  
2 programs.

3 **SEC. 3. CONTROLLED SUBSTANCE MONITORING PROGRAM.**

4 Part P of title III of the Public Health Service Act  
5 (42 U.S.C. 280g et seq.) is amended by adding after sec-  
6 tion 399N the following:

7 **“SEC. 399O. CONTROLLED SUBSTANCE MONITORING PRO-**  
8 **GRAM.**

9 “(a) GRANTS.—

10 “(1) IN GENERAL.—Each fiscal year, the Sec-  
11 retary shall award a grant to each State with an ap-  
12 plication approved under this section to enable the  
13 State—

14 “(A) to establish and implement a State  
15 controlled substance monitoring program; or

16 “(B) to make improvements to an existing  
17 State controlled substance monitoring program.

18 “(2) DETERMINATION OF AMOUNT.—

19 “(A) MINIMUM AMOUNT.—In making pay-  
20 ments under a grant under paragraph (1) for  
21 a fiscal year, the Secretary shall allocate to  
22 each State with an application approved under  
23 this section an amount that equals 1.0 percent  
24 of the amount appropriated to carry out this  
25 section for that fiscal year.



1           “(B) ADDITIONAL AMOUNTS.—In making  
2           payments under a grant under paragraph (1)  
3           for a fiscal year, the Secretary shall allocate to  
4           each State with an application approved under  
5           this section an additional amount which bears  
6           the same ratio to the amount appropriated to  
7           carry out this section for that fiscal year and  
8           remaining after amounts are made available  
9           under subparagraph (A) as the number of phar-  
10          macies of the State bears to the number of  
11          pharmacies of all States with applications ap-  
12          proved under this section (as determined by the  
13          Secretary), except that the Secretary may ad-  
14          just the amount allocated to a State under this  
15          subparagraph after taking into consideration  
16          the budget cost estimate for the State’s con-  
17          trolled substance monitoring program.

18          “(3) TERM OF GRANTS.—Grants awarded  
19          under this section shall be obligated in the year in  
20          which funds are allotted.

21          “(b) DEVELOPMENT OF MINIMUM REQUIRE-  
22          MENTS.—Prior to awarding a grant under this section,  
23          and not later than 6 months after the date on which funds  
24          are first appropriated to carry out this section, the Sec-  
25          retary shall, after publishing in the Federal Register pro-



1 posed minimum requirements and receiving public com-  
2 ments, establish minimum requirements for criteria to be  
3 used by States for purposes of clauses (ii), (v), (vi), and  
4 (vii) of subsection (c)(1)(A).

5 “(c) APPLICATION APPROVAL PROCESS.—

6 “(1) IN GENERAL.—To be eligible to receive a  
7 grant under this section, a State shall submit an ap-  
8 plication to the Secretary at such time, in such man-  
9 ner, and containing such assurances and information  
10 as the Secretary may reasonably require. Each such  
11 application shall include—

12 “(A) with respect to a State that intends  
13 to use funds under the grant as provided for in  
14 subsection (a)(1)(A)—

15 “(i) a budget cost estimate for the  
16 controlled substance monitoring program  
17 to be implemented under the grant;

18 “(ii) criteria for security for informa-  
19 tion handling and for the database main-  
20 tained by the State under subsection (e)  
21 generally including efforts to use appro-  
22 priate encryption technology or other ap-  
23 propriate technology to protect the security  
24 of such information;



1 “(iii) an agreement to adopt health in-  
2 formation interoperability standards, in-  
3 cluding health vocabulary and messaging  
4 standards, that are consistent with any  
5 such standards generated or identified by  
6 the Secretary or his or her designee;

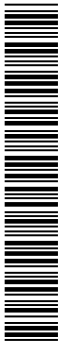
7 “(iv) criteria for meeting the uniform  
8 electronic format requirement of subsection  
9 (h);

10 “(v) criteria for availability of infor-  
11 mation and limitation on access to pro-  
12 gram personnel;

13 “(vi) criteria for access to the data-  
14 base, and procedures to ensure that infor-  
15 mation in the database is accurate;

16 “(vii) criteria for the use and disclo-  
17 sure of information, including a description  
18 of the certification process to be applied to  
19 requests for information under subsection  
20 (f);

21 “(viii) penalties for the unauthorized  
22 use and disclosure of information main-  
23 tained in the State controlled substance  
24 monitoring program in violation of applica-  
25 ble State law or regulation;



1 “(ix) information on the relevant  
2 State laws, policies, and procedures, if any,  
3 regarding purging of information from the  
4 database; and

5 “(x) assurances of compliance with all  
6 other requirements of this section; or

7 “(B) with respect to a State that intends  
8 to use funds under the grant as provided for in  
9 subsection (a)(1)(B)—

10 “(i) a budget cost estimate for the  
11 controlled substance monitoring program  
12 to be improved under the grant;

13 “(ii) a plan for ensuring that the  
14 State controlled substance monitoring pro-  
15 gram is in compliance with the criteria and  
16 penalty requirements described in clauses  
17 (ii) through (viii) of subparagraph (A);

18 “(iii) a plan to enable the State con-  
19 trolled substance monitoring program to  
20 achieve interoperability with at least one  
21 other State controlled substance moni-  
22 toring program; and

23 “(iv) assurances of compliance with  
24 all other requirements of this section or a  
25 statement describing why such compliance



1 is not feasible or is contrary to the best in-  
2 terests of public health in such State.

3 “(2) STATE LEGISLATION.—As part of an ap-  
4 plication under paragraph (1), the Secretary shall  
5 require a State to demonstrate that the State has  
6 enacted legislation or regulations to permit the im-  
7 plementation of the State controlled substance moni-  
8 toring program and the imposition of appropriate  
9 penalties for the unauthorized use and disclosure of  
10 information maintained in such program.

11 “(3) INTEROPERABILITY.—If a State that sub-  
12 mits an application under this subsection geographi-  
13 cally borders another State that is operating a con-  
14 trolled substance monitoring program under sub-  
15 section (a)(1) on the date of submission of such ap-  
16 plication, and such applicant State has not achieved  
17 interoperability for purposes of information sharing  
18 between its monitoring program and the monitoring  
19 program of such border State, such applicant State  
20 shall, as part of the plan under paragraph  
21 (1)(B)(iii), describe the manner in which the appli-  
22 cant State will achieve interoperability between the  
23 monitoring programs of such States.



1           “(4) APPROVAL.—If a State submits an appli-  
2           cation in accordance with this subsection, the Sec-  
3           retary shall approve such application.

4           “(5) RETURN OF FUNDS.—If the Secretary  
5           withdraws approval of a State’s application under  
6           this section, or the State chooses to cease to imple-  
7           ment or improve a controlled substance monitoring  
8           program under this section, a funding agreement for  
9           the receipt of a grant under this section is that the  
10          State will return to the Secretary an amount which  
11          bears the same ratio to the overall grant as the re-  
12          maining time period for expending the grant funds  
13          bears to the overall time period for expending the  
14          grant (as specified by the Secretary at the time of  
15          the grant).

16          “(d) REPORTING REQUIREMENTS.—In implementing  
17          or improving a controlled substance monitoring program  
18          under this section, a State shall comply, or with respect  
19          to a State that applies for a grant under subsection  
20          (a)(1)(B) submit to the Secretary for approval a state-  
21          ment of why such compliance is not feasible or is contrary  
22          to the best interests of public health in such State, with  
23          the following:

24                 “(1) The State shall require dispensers to re-  
25                 port to such State each dispensing in the State of





1 a controlled substance to an ultimate user not later  
2 than 1 week after the date of such dispensing.

3 “(2) The State may exclude from the reporting  
4 requirement of this subsection—

5 “(A) the direct administration of a con-  
6 trolled substance to the body of an ultimate  
7 user;

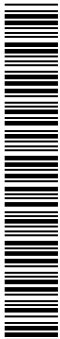
8 “(B) the dispensing of a controlled sub-  
9 stance in a quantity limited to an amount ade-  
10 quate to treat the ultimate user involved for 48  
11 hours or less; or

12 “(C) the administration or dispensing of a  
13 controlled substance in accordance with any  
14 other exclusion identified by the Secretary for  
15 purposes of this paragraph.

16 “(3) The information to be reported under this  
17 subsection with respect to the dispensing of a con-  
18 trolled substance shall include the following:

19 “(A) Drug Enforcement Administration  
20 Registration Number (or other identifying num-  
21 ber used in lieu of such Registration Number)  
22 of the dispenser.

23 “(B) Drug Enforcement Administration  
24 Registration Number (or other identifying num-  
25 ber used in lieu of such Registration Number)



1 and name of the practitioner who prescribed the  
2 drug.

3 “(C) Name, address, and telephone num-  
4 ber of the ultimate user or such contact infor-  
5 mation of the ultimate user as the Secretary de-  
6 termines appropriate.

7 “(D) Identification of the drug by a na-  
8 tional drug code number.

9 “(E) Quantity dispensed.

10 “(F) Number of refills ordered.

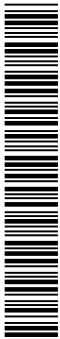
11 “(G) Whether the drug was dispensed as a  
12 refill of a prescription or as a first-time request.

13 “(H) Date of the dispensing.

14 “(I) Date of origin of the prescription.

15 “(J) Such other information as may be re-  
16 quired by State law to be reported under this  
17 subsection.

18 “(4) The State shall require dispensers to re-  
19 port information under this section in accordance  
20 with the electronic format specified by the Secretary  
21 under subsection (h), except that the State may  
22 waive the requirement of such format with respect to  
23 an individual dispenser that is unable to submit such  
24 information by electronic means.



1       “(e) DATABASE.—In implementing or improving a  
2 controlled substance monitoring program under this sec-  
3 tion, a State shall comply with the following:

4           “(1) The State shall establish and maintain an  
5 electronic database containing the information re-  
6 ported to the State under subsection (d).

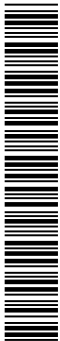
7           “(2) The database must be searchable by any  
8 field or combination of fields.

9           “(3) The State shall include reported informa-  
10 tion in the database in a manner consistent with cri-  
11 teria established by the Secretary, with appropriate  
12 safeguards for ensuring the accuracy and complete-  
13 ness of the database.

14           “(4) The State shall take appropriate security  
15 measures to protect the integrity of, and access to,  
16 the database.

17       “(f) USE AND DISCLOSURE OF INFORMATION.—

18           “(1) IN GENERAL.—Subject to subsection (g),  
19 in implementing or improving a controlled substance  
20 monitoring program under this section, a State may  
21 disclose information from the database established  
22 under subsection (e) and, in the case of a request  
23 under subparagraph (D), summary statistics of such  
24 information, only in response to a request by—



1           “(A) a practitioner (or the agent thereof)  
2           who certifies, under the procedures determined  
3           by the State, that the requested information is  
4           for the purpose of providing medical or pharma-  
5           ceutical treatment or evaluating the need for  
6           such treatment to a bona fide current patient;

7           “(B) any local, State, or Federal law en-  
8           forcement, narcotics control, licensure, discipli-  
9           nary, or program authority, who certifies, under  
10          the procedures determined by the State, that  
11          the requested information is related to an indi-  
12          vidual investigation or proceeding involving the  
13          unlawful diversion or misuse of a schedule II,  
14          III, or IV substance, and such information will  
15          further the purpose of the investigation or as-  
16          sist in the proceeding;

17          “(C) the controlled substance monitoring  
18          program of another State or group of States  
19          with whom the State has established an inter-  
20          operability agreement;

21          “(D) any agent of the Department of  
22          Health and Human Services, a State medicaid  
23          program, a State health department, or the  
24          Drug Enforcement Administration who certifies  
25          that the requested information is necessary for



1 research to be conducted by such department,  
2 program, or administration, respectively, and  
3 the intended purpose of the research is related  
4 to a function committed to such department,  
5 program, or administration by law that is not  
6 investigative in nature; or

7 “(E) an agent of the State agency or enti-  
8 ty of another State that is responsible for the  
9 establishment and maintenance of that State’s  
10 controlled substance monitoring program, who  
11 certifies that—

12 “(i) the State has an application ap-  
13 proved under this section; and

14 “(ii) the requested information is for  
15 the purpose of implementing the State’s  
16 controlled substance monitoring program  
17 under this section.

18 “(2) DRUG DIVERSION.—In consultation with  
19 practitioners, dispensers, and other relevant and in-  
20 terested stakeholders, a State receiving a grant  
21 under subsection (a)—

22 “(A) shall establish a program to notify  
23 practitioners and dispensers of information that  
24 will help identify and prevent the unlawful di-  
25 version or misuse of controlled substances; and



1           “(B) may, to the extent permitted under  
2           State law, notify the appropriate authorities re-  
3           sponsible for carrying out drug diversion inves-  
4           tigations if the State determines that informa-  
5           tion in the database maintained by the State  
6           under subsection (e) indicates an unlawful di-  
7           version or abuse of a controlled substance.

8           “(g) LIMITATIONS.—In implementing or improving a  
9           controlled substance monitoring program under this sec-  
10          tion, a State—

11           “(1) shall limit the information provided pursu-  
12          ant to a valid request under subsection (f)(1) to the  
13          minimum necessary to accomplish the intended pur-  
14          pose of the request; and

15           “(2) shall limit information provided in re-  
16          sponse to a request under subsection (f)(1)(D) to  
17          nonidentifiable information.

18           “(h) ELECTRONIC FORMAT.—The Secretary shall  
19          specify a uniform electronic format for the reporting, shar-  
20          ing, and disclosure of information under this section.

21           “(i) RULES OF CONSTRUCTION.—

22           “(1) FUNCTIONS OTHERWISE AUTHORIZED BY  
23          LAW.—Nothing in this section shall be construed to  
24          restrict the ability of any authority, including any  
25          local, State, or Federal law enforcement, narcotics



1 control, licensure, disciplinary, or program authority,  
2 to perform functions otherwise authorized by law.

3 “(2) NO PREEMPTION.—Nothing in this section  
4 shall be construed as preempting any State law, ex-  
5 cept that no such law may relieve any person of a  
6 requirement otherwise applicable under this Act.

7 “(3) ADDITIONAL PRIVACY PROTECTIONS.—  
8 Nothing in this section shall be construed as pre-  
9 empting any State from imposing any additional pri-  
10 vacy protections.

11 “(4) FEDERAL PRIVACY REQUIREMENTS.—  
12 Nothing in this section shall be construed to super-  
13 sede any Federal privacy or confidentiality require-  
14 ment, including the regulations promulgated under  
15 section 264(c) of the Health Insurance Portability  
16 and Accountability Act of 1996 (Public Law 104–  
17 191; 110 Stat. 2033) and section 543 of the Public  
18 Health Service Act.

19 “(5) NO FEDERAL PRIVATE CAUSE OF AC-  
20 TION.—Nothing in this section shall be construed to  
21 create a Federal private cause of action.

22 “(j) STUDIES AND REPORTS.—

23 “(1) IMPLEMENTATION REPORT.—

24 “(A) IN GENERAL.—Not later than 180  
25 days after the date of enactment of this section,



1 the Secretary, based on a review of existing  
2 State controlled substance monitoring programs  
3 and other relevant information, shall determine  
4 whether the implementation of such programs  
5 has had a substantial negative impact on—

6 “(i) patient access to treatment, in-  
7 cluding therapy for pain or controlled sub-  
8 stance abuse;

9 “(ii) pediatric patient access to treat-  
10 ment; or

11 “(iii) patient enrollment in research or  
12 clinical trials in which, following the pro-  
13 tocol that has been approved by the rel-  
14 evant institutional review board for the re-  
15 search or clinical trial, the patient has ob-  
16 tained a controlled substance from either  
17 the scientific investigator conducting such  
18 research or clinical trial or the agent there-  
19 of.

20 “(B) ADDITIONAL CATEGORIES OF EXCLU-  
21 SION.—If the Secretary determines under sub-  
22 paragraph (A) that a substantial negative im-  
23 pact has been demonstrated with regard to one  
24 or more of the categories of patients described  
25 in such subparagraph, the Secretary shall iden-





1           tify additional appropriate categories of exclu-  
2           sion from reporting as authorized under sub-  
3           section (d)(2)(C).

4           “(2) PROGRESS REPORT.—Not later than 3  
5           years after the date on which funds are first appro-  
6           priated under this section, the Secretary shall—

7                   “(A) complete a study that—

8                           “(i) determines the progress of States  
9                           in establishing and implementing con-  
10                          trolled substance monitoring programs  
11                          under this section;

12                          “(ii) provides an analysis of the extent  
13                          to which the operation of controlled sub-  
14                          stance monitoring programs have reduced  
15                          inappropriate use, abuse, or diversion of  
16                          controlled substances or affected patient  
17                          access to appropriate pain care in States  
18                          operating such programs;

19                          “(iii) determines the progress of  
20                          States in achieving interoperability between  
21                          controlled substance monitoring programs,  
22                          including an assessment of technical and  
23                          legal barriers to such activities and rec-  
24                          ommendations for addressing these bar-  
25                          riers;

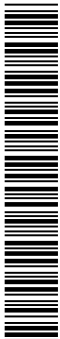


1 “(iv) determines the feasibility of im-  
2 plementing a real-time electronic controlled  
3 substance monitoring program, including  
4 the costs associated with establishing such  
5 a program;

6 “(v) provides an analysis of the pri-  
7 vacy protections in place for the informa-  
8 tion reported to the controlled substance  
9 monitoring program in each State receiv-  
10 ing a grant for the establishment or oper-  
11 ation of such program, and any rec-  
12 ommendations for additional requirements  
13 for protection of this information;

14 “(vi) determines the feasibility of im-  
15 plementing technological alternatives to  
16 centralized data storage, such as peer-to-  
17 peer file sharing or data pointer systems,  
18 in controlled substance monitoring pro-  
19 grams and the potential for such alter-  
20 natives to enhance the privacy and security  
21 of individually identifiable data; and

22 “(vii) evaluates the penalties that  
23 States have enacted for the unauthorized  
24 use and disclosure of information main-  
25 tained in the controlled substance moni-



1                   toring program, and reports on the criteria  
2                   used by the Secretary to determine wheth-  
3                   er such penalties qualify as appropriate  
4                   pursuant to this section; and

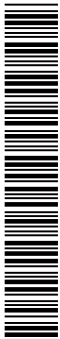
5                   “(B) submit a report to the Congress on  
6                   the results of the study.

7           “(k) PREFERENCE.—Beginning 3 years after the  
8   date on which funds are first appropriated to carry out  
9   this section, the Secretary, in awarding any competitive  
10   grant that is related to drug abuse (as determined by the  
11   Secretary) and for which only States are eligible to apply,  
12   shall give preference to any State with an application ap-  
13   proved under this section. The Secretary shall have the  
14   discretion to apply such preference to States with existing  
15   controlled substance monitoring programs that meet min-  
16   imum requirements under this section or to States that  
17   put forth a good faith effort to meet those requirements  
18   (as determined by the Secretary).

19           “(l) ADVISORY COUNCIL.—

20                   “(1) ESTABLISHMENT.—A State may establish  
21   an advisory council to assist in the establishment,  
22   implementation, or improvement of a controlled sub-  
23   stance monitoring program under this section.

24                   “(2) LIMITATION.—A State may not use  
25   amounts received under a grant under this section



1 for the operations of an advisory council established  
2 under paragraph (1).

3 “(3) SENSE OF CONGRESS.—It is the sense of  
4 the Congress that, in establishing an advisory coun-  
5 cil under this subsection, a State should consult with  
6 appropriate professional boards and other interested  
7 parties.

8 “(m) DEFINITIONS.—For purposes of this section:

9 “(1) The term ‘bona fide patient’ means an in-  
10 dividual who is a patient of the practitioner involved.

11 “(2) The term ‘controlled substance’ means a  
12 drug that is included in schedule II, III, or IV of  
13 section 202(c) of the Controlled Substance Act.

14 “(3) The term ‘dispense’ means to deliver a  
15 controlled substance to an ultimate user by, or pur-  
16 suant to the lawful order of, a practitioner, irrespec-  
17 tive of whether the dispenser uses the Internet or  
18 other means to effect such delivery.

19 “(4) The term ‘dispenser’ means a physician,  
20 pharmacist, or other person that dispenses a con-  
21 trolled substance to an ultimate user.

22 “(5) The term ‘interoperability’ with respect to  
23 a State controlled substance monitoring program  
24 means the ability of the program to electronically  
25 share reported information, including each of the re-



1       quired report components described in subsection  
2       (d), with another State if the information concerns  
3       either the dispensing of a controlled substance to an  
4       ultimate user who resides in such other State, or the  
5       dispensing of a controlled substance prescribed by a  
6       practitioner whose principal place of business is lo-  
7       cated in such other State.

8           “(6) The term ‘nonidentifiable information’  
9       means information that does not identify a practi-  
10      tioner, dispenser, or an ultimate user and with re-  
11      spect to which there is no reasonable basis to believe  
12      that the information can be used to identify a practi-  
13      tioner, dispenser, or an ultimate user.

14          “(7) The term ‘practitioner’ means a physician,  
15      dentist, veterinarian, scientific investigator, phar-  
16      macy, hospital, or other person licensed, registered,  
17      or otherwise permitted, by the United States or the  
18      jurisdiction in which he or she practices or does re-  
19      search, to distribute, dispense, conduct research with  
20      respect to, administer, or use in teaching or chemical  
21      analysis, a controlled substance in the course of pro-  
22      fessional practice or research.

23          “(8) The term ‘State’ means each of the 50  
24      States and the District of Columbia.



1           “(9) The term ‘ultimate user’ means a person  
2           who has obtained from a dispenser, and who pos-  
3           sesses, a controlled substance for his or her own use,  
4           for the use of a member of his or her household, or  
5           for the use of an animal owned by him or her or by  
6           a member of his or her household.

7           “(n) AUTHORIZATION OF APPROPRIATIONS.—To  
8           carry out this section, there are authorized to be  
9           appropriated—

10           “(1) \$15,000,000 for each of fiscal years 2006  
11           and 2007; and

12           “(2) \$10,000,000 for each of fiscal years 2008,  
13           2009, and 2010.”.

